DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 23, 2015

Philips Medical Systems
Carlene Comrie
Director, Regulatory Affairs
22100 Bothel Everett Way
Bothel, WA 98021

Re: K133659
Trade/Device Name: HeartStart XL+ Defibrillator/Monitor with End-Tidal CO_2 Monitoring
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LDD, DRO, MHX, DXN, CCK, DQA
Dated: December 19, 2014
Received: December 24, 2014

Dear Carlene Comrie,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PHILIPS

Indications for Use

510(k) Number (if known): K133659

Device Name: HeartStart XL+ Defibrillator/Monitor with End Tidal CO_2 Monitoring

Indications for Use: The HeartStart XL+ is a defibrillator/monitor. The device is for use by qualified medical personnel trained in the operation of the device and certified by training in basic life support, advanced life support or defibrillation. It must be used by or on the order of a physician.

AED Therapy: AED mode is used in the presence of suspected cardiac arrest on patients that are unresponsive, not breathing and pulseless.

Manual Defribillation: Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronous defibrillation (cardioversion) is indicated for termination of certain atrial and ventricular arrhythmias.

Non-Invasive External Pacing: The pacing option is indicated for treating patients with symptomatic bradycardia.

Pulse Oximetry: The SpO2 option is indicated for use when it is beneficial to assess the patient's oxygen saturation level.

Non-Invasive Blood Pressure Monitoring: The NBP option is indicated for non-invasive measurement of a patient's arterial blood pressure.

End-Tidal CO_2: The EtCO2 option is intended for noninvasive monitoring of a patient's exhaled carbon dioxide and to provide a respiration rate.

ECG Monitoring: ECG monitoring is indicated to be used for monitoring, alarming and recording of the patient's heart rate and morphology.

Prescription Use __X__	AND/OR	Over The Counter Use_____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitter: Philips Medical Systems
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Date Prepared: January 22, 2015

Trade Name: HeartStart XL+ with End-Tidal Carbon Dioxide Monitoring Defibrillator/Monitor

Common Name: Automatic External Defibrillator

Classification Name: Automatic External Defibrillator

Classification Regulation: 21 CFR 870.5310

Device Class: Class III

Product Code: MKJ, LDD, DRO, MHX, DXN, CCK, DQA

Predicate Device: PhilipsHeartStart XL+ Defibrillator Monitor (K110825)
Philips HeartStart MRx Defibrillator/Monitor (K130153)
Zoll E Series Defibrillator/Monitor with Intubation Assist Option (K080903)
Zoll R Series with NIBPand ETCO2 Option (K090989)

Device Description: The Philips HeartStart XL+ with End-Tidal Carbon Dioxide Monitoring Defibrillator/Monitor is a modification of the FDA cleared HeartStart XL+ Defibrillator/Monitor. This function of the XL+ modification is to measure the partial

pressure of carbon dioxide in a sample of the patient's exhaled breath. The HeartStart XL+ may be used to monitor carbon dioxide in both intubated and non-intubated patients.

The partial pressure of carbon dioxide is derived by multiplying the measured carbon dioxide concentration with the ambient pressure. From the partial pressure measurement, the end-tidal carbon dioxide (EtCO2) is derived.

EtCO2 is the peak CO2 value measured during expiration. It is used to monitor the patient's respiratory status. The EtCO2 measurement uses a technique based on the absorption of infrared radiation by some gases. It indicates the change in:

• The elimination of CO2.
• The delivery of O2 to the lungs.

The CO2 monitoring function of the HeartStart XL+ provides an EtCO2 value, a CO2 waveform (Capnogram), and an airway respiration rate (AwRR). The AwRR relies onCO2 functionality to identify valid breaths for numeric display and alarm conditions such as Apnea.

Statement of Intended Use:

The HeartStart XL+ is intended for use in a hospital setting by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced life support or defibrillation.

When operating as a semi-automated external defibrillator in AED Mode, the HeartStart XL+ is suitable for use by medical personnel trained in basic life support that includes the use of an AED.

When operating in Monitor, Manual Defibrillation or Pacing modes, the HeartStart XL+ is suitable for use by healthcare professionals trained in advance life support.

Statement(s) of Indication for Use:

The HeartStart XL+ is a defibrillator/monitor. The device is for use by qualified medical personnel trained in the operation of the device and certified by training in basic life support, advanced life support or defibrillation. It must be used by or on the order of a physician.

AED Therapy

AED mode is used in the presence of suspected cardiac arrest on patients that are unresponsive, not breathing and pulseless.

Manual Defibrillation

Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronous defibrillation (cardioversion) is indicated for termination of certain atrial and ventricular arrhythmias.

Non-Invasive External Pacing

The pacing option is indicated for treating patients with symptomatic bradycardia.

Pulse Oximetry

The SpO2 option is indicated for use when it is beneficial to assess the patient's oxygen saturation level.

Non-Invasive Blood Pressure Monitoring

The NBP option is indicated for non-invasive measurement of a patient's arterial blood pressure.

End-tidal CO2

The EtCO2 option is intended for noninvasive monitoring of a patient's exhaled carbon dioxide and to provide a respiration rate.

ECG Monitoring

ECG monitoring is indicated to be used for monitoring, alarming and recording of the patient's heart rate and morphology.

Summary of Technological Characteristics:

In addition to being technologically equivalent to the predicate devices, the HeartStart XL+ with End-Tidal Carbon Dioxide Monitoring Defibrillator/Monitor has been subjected to performance and usability testing and it has been determined that the HeartStart XL+ with End-Tidal Carbon Dioxide Monitoring Defibrillator/Monitor suitable for its

intended use.

Summary of Non-clinical Data:

Verification and validation activities were completed which included safety and bench testing. HeartStart XL+ with End-Tidal Carbon Dioxide Monitoring Defibrillator/Monitor was tested according to the applicable EMC, safety, performance standards as described below:

Standard	Type
IEC 60601-1 Medical Electrical Equipment- Part 1: General Requirements for basic safety and essential performance	Basic Safety and Essential Performance
IEC 60601-1-2 Medical Electrical Equipment- General Requirements for safety- Collateral standard: Electromagnetic compatibility	Electromagnetic Compatibility
IEC 60601-2-4 Medical Electrical Equipment- Part 2-4: Particular requirements for basic safety of cardiac defibrillators	Cardiac Defibrillators
IEC 60601-1-8 Medical electrical equipment: General requirements tests and guidance for alarm systems	Alarms
IEC 60601-2-30 Medical electrical equipment: Particular requirements for the safety, automatic cycling non-invasive blood pressure monitoring equipment	NBP (Non-Invasive Blood Pressure)
IEC 60601-2-27 Medical electrical equipment: Particular requirements for the safety, specification for electrocardiographic monitoring equipment	ECG
EN ISO 9919 Medical electrical equipment Part 2-27: Particular requirements for the basic safety of pulse	Basic Safety and Essential Performance of Pulse Oximeter Equipment

Oximeter equipment.	
EN ISO 21647 Medical electrical equipment – Particular requirements for the basic safety and essential of respiratory gas monitors	Basic Safety of respiratory gas monitors.

The non-clinical testing was completed with passing results according to its Pass/Fail criteria. The Philips HeartStart XL+ with End-Tidal Carbon Dioxide Monitoring Defibrillator/Monitor is manufactured under the same conditions, using the similar processes and identical materials, as the Philips HeartStart XL+ Defibrillator/Monitor, the legally marketed Philips Medical Systems predicate device. In addition to being technologically equivalent, the indications for use have not changed.

Clinical Testing: No clinical studies were necessary to demonstrate substantial equivalence

Conclusion: Philips considers that the Philips HeartStart XL+ with End-Tidal Carbon Dioxide Monitoring Defibrillator/Monitor to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).